This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-53 canceled.

54(new). An assay method for the determination of holo-transcobalamin II (holo-TC II)in a body sample capable of detecting holo-TC II in said body sample at a concentration as low as 35 pM, said method comprising contacting a cell free sample of a body fluid with an immobilised or immobilizable specific binding antibody or antibody fragment for transcobalamin II (TC II) having an affinity constant of at least 10^9M^{-1} and a cross reactivity with haptocorrin of less than 1%, whereby to form bound TC II, separating a ligand bound fraction from a non-ligand bound fraction, such that at least 80% of TC II present within said cell free sample is contained within said ligand bound fraction, and determining the holo-TC II content in said body sample by dissociating bound cobalamin from the holo-TC II in the bound fraction and determining the concentration of the cobalamin released, said dissociation being so affected that the concentration of the released cobalamin is at least 3 times greater than the concentration of holo-TC II in the initial sample.

55(new). An assay method as claimed in claim 54 wherein said assay is capable of detecting holo-TC II in said body sample at a concentration as low as 9 pM.

56(new). An assay method as claimed in claim 54 wherein said assay is effected to analysis by an automated process.

57(new). An assay method as claimed in claim 54 wherein said specific binding ligand is a monoclonal antibody.

58(new). An assay method as claimed in claim 54 wherein the different cobalamin forms are converted to the less light sensitive cyanocobalamin by treatment with KCN prior to contacting said sample with a specific binding ligand.

59(new). An assay method as claimed in claim 54 wherein said cobalamin arising from the bound holo-TC II is measured by a competition assay performed by contacting an immobilised binding partner for cobalamin with the dissociated cobalamin of the sample in the presence of labelled ligand which competes with the isolated cobalamin for binding to the immobilised binding partners.

60(new). An assay method as claimed in claim 54 further comprising a preliminary separation step in which the cell free sample is contacted with an immobilized or immobilizable specific binding ligand for haptocorrin wherein said preliminary step is carried out prior to contacting said cell free sample with said specific binding ligand.

61(new). An assay method as claimed in claim 51 wherein the affinity constant of said antibody or antibody fragment is greater than $2x10^{9}M^{-1}$.

62(new). An assay method as claimed in claim 61 wherein the affinity constant is greater than $10^{10}M^{-1}$.

63(new). An assay method as claimed in claim 62 wherein the affinity constant is greater than $10^{11}M^{-1}$.

64(new). An assay method as claimed in claim 54 wherein the degree of cross-reactivity is between 0.1% and 1%.

65(new). An assay method as claimed in claim 64 wherein the degree of cross-reactivity is less than 0.1%.

66(new). An assay method as claimed in claim 54 wherein the concentration of the released cobalamin is at least 5-fold greater than the concentration of holo-TC II in the initial sample.

67(new). An assay method as claimed in claim 54 wherein the concentration of the released cobalamin is at least 10-fold greater than the concentration of holo-TC II in the initial sample.

68(new). An assay method as claimed in claim 54 wherein said body sample is selected from the group consisting of seminal fluid, cerebro-spinal fluid, amniotic fluid and blood derived samples.

69(new). An assay method as claimed in claim 68 wherein said sample is serum or plasma.

70(new). An assay method as claimed in claim 54 wherein said bound fraction is separated from said unbound fraction by precipitation, centrifugation, filtration or chromatographic methods.

71(new). An assay method as claimed in claim 54 wherein said specific binding ligands are immobilised on a particulate solid phase support.

72(new). An assay method as claimed in claim 71 wherein said solid support comprises magnetic beads.

73(new). A kit for use in a diagnostic assay according to claim 54, comprising:

an immobilized or immobilizable specific binding ligand for TC II or holo-TC II;

a plurality of holo-TC II solutions of known concentration;

a release agent to release cobalamin from holo-TC; and

optionally a labelled ligand